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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/13/2004

Akihiko Yanaga

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

11/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,985

Applicant(s)

YANAGA, AKIHIKO

Examiner

Christopher A. Flory

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,8,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 November 2007 has been entered.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by Granzotto et al. (US Patent 6,757,392, hereinafter Granzotto'392) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392, or Granzotto'392 in view of Reinhold, Jr. (US Patent 5,339,823, hereinafter referred to as Reinhold'823), or Granzotto'392 in view of Marangoni (US 4,535,783, hereinafter Marangoni'783).

Regarding claim 1, Granzotto'392 discloses an electrocardiograph (column 1, lines 60-67) comprising a body case (Fig. 1, headpiece 1) which is held on a chest portion of a subject (ABSTRACT; column 3, lines 8-22); a common electrode provided on

a back surface of said body case (Fig. 4, fixed electrode 16); a pair of arm portions which extend from said body case (Fig. 4, arms 18); electrodes for detecting electrocardiographic complex which are provided in both end portions of said pair of said arm portions respectively (Fig. 4, electrodes 17; column 2, lines 1-7); a detecting means for detecting electrocardiographic complex based on signals detected by said electrodes (column 4, lines 51-59); a display means for displaying said electrocardiographic means (Fig. 3, LCD 11 displays the electrocardiographic complex and heart rate); a transmitting means for transmitting said electrocardiographic complex (LCD 11 can be considered a transmitting means; likewise, circuitry or wiring between the disclosed memory and display constitutes a transmitting means.

Further regarding the switching means of claim 1, Granzotto'392 discloses switching contacts at pivot joints 19 for the purpose of connecting electrodes 17 to the main body electrode only when the arms are in a fully extended position (column 4, lines 7-27), while the unit will otherwise function as a passive auscultatory device. This can clearly be seen as a disclosure of a switching means that would start detection, display and transmission of the electrocardiographic complex to the LCD, where data would only be recorded if the device were placed in contact with the chest portion of the subject. Granzotto'392 further discloses that the arm parts are molded of a flexible plastic and incline at an obtuse angle which changes under pressure on the stethoscope head, and further that such manual pressure on the stethoscope head is necessary to achieve firm contact of the electrodes to detect, display and record the electrocardiographic information (column 4, lines 1-47, emphasis on lines 28-47). This

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can reasonably be considered a disclosure of push-down switches either in that the arm pivot switching contacts or the electrodes themselves must be pushed down with this manual pressure in order to make contact with all electrodes to the skin in order to detect, display and record the electrocardiographic complex, such that when this push-down pressure is not applied, contact is not made and the ECG complex is not detected.

Alternatively, push-down switches located in the electrode contacts of externally applied ECG and heart rate acquiring electrode devices are well-known in the art (e.g. treadmills, bathroom scales, or other devices where bi-point electrocardiographic data acquisition is desired through a gripping or weight-bearing means) as a simple to manufacture and reliable means of conserving battery or device power by disconnecting the ECG circuit when the user is not applying gripping or weight-bearing pressure on the device since no useful data could be collected in such a situation. Simultaneous application of pressure to both electrode contacts in these configurations initiates ECG collection, analysis and readout. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Granzotto'392 with push-down switches located in the electrodes to provide Granzotto'392 with the same well-known advantages of conserving device power by only collecting ECG data when pressure is applied to the electrodes to signify a significant connection to a patient for whom collection of ECG data is desired.

Still further in the alternative, Reinhold'823 teaches a device wherein human pressure is applied to engage an array of electrodes with the skin of the chest of an

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individual to place the electrodes in an operative relation to obtain electrocardiogram data from the individual (abstract; column 2, lines 20-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the pressure-activated electrodes and control protocol as taught by Reinhold'823 to provide Granzotto'329 with the same advantage of engaging an electrode array to the chest in an operative relation so as to be able to effectively obtain electrocardiogram data.

Still further in the alternative, Marangoni'783 teaches an electrocardiography recorder in which electrodes (Fig. 1A, electrodes 7 and 8) are disposed over an pressure switch (Fig. 4, switch 21) in such a way that the switch is actuated when the contacts are brought into contact with the skin with a predetermined minimum satisfactory pressure to initiate recording of ECG data, and not record ECG data otherwise (column 4, lines 19-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Granzotto'392 with the press-down electrode switching means as taught by Marangoni'783 to provide Granzotto'392 with the same advantage of recording ECG data only when satisfactory pressure contact between the electrodes and the skin have been made.

Regarding claims 7 and 8, Granzotto'392 shows said body case suspended from a neck of said subject by a suspending means (Fig. 1, flexible bows 31; column 2, lines 3-39).

4. Claims 4, 5, 10 and 11 stand rejected under 35 U.S.C. 102(b) as anticipated by Granzotto'392 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto'392 in view of Reinhold'823, or still alternatively as obvious over Granzotto'392 in view of Marangioni'783 further in view of Reinhold'823.

Regarding claims 4 and 5, it is evident from the scope of the disclosure in Granzotto'392 that non-paste electrodes are inherently necessary for proper function of the Granzotto'392 device. It is well known that stethoscopes operate by being placed temporarily on the chest of a subject and are held there by human force rather than adhesive means. Granzotto'392 further discloses that electrodes 17 are moveable (column 4, lines 1-27) and applied through pressure (column 4, lines 45-47) rather than adhesive means.

Alternatively in the same field of endeavor, Reinhold'823 teaches the use of non-adhesive precordial electrodes on an electrocardiograph device in which human pressure is applied to engage the array of six precordial electrodes with the skin of the chest of the individual in an operative relation (ABSTRACT; column 4, lines 54-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the non-adhesive electrodes of Reinhold'823 to provide the Granzotto'392 system with the advantage of temporarily applying the device to a patient in an operative relation with human pressure contact (motivation to combine provided by Reinhold'823 ABSTRACT; column 4, lines 54-66).

Regarding claim 10, Granzotto'392 shows said body case suspended from a neck of said subject by a suspending means (Fig. 1, flexible bows 31; column 2, lines 3-39).

Regarding claim 11, the suspending means of Granzotto et al. is considered to be detachable because the bows 31 are made of a rigidly flexible material known in the art which hold the device on the neck of a user while in their resting configuration, but can be manually separated to allow removal of the device from the neck. The suspending means of Granzotto et al. is detachable to said body case because the bows 31 could be physically removed from the chest-piece 2 without altering in any way the function of the electrocardiograph subsystem.

Alternatively in the same field of endeavor, Reinhold'823 teaches an electrocardiograph device employing a lanyard for engagement around the neck of the user (column 5, lines 1-20). It is well known that a lanyard, such as one used on a set of keys or on a personal camera, comprises a separate flexible loop body (typically fabric) that is attached in a releasable manner to the main body of a device, either by tying through a hole in the device body, attaching to the device body by a key ring, or releasably inserting a male connector portion into a compatible female connector portion. This establishes a detachable quality to the lanyard taught by Reinhold'823. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto'392 with the detachable lanyard as taught by Reinhold'823 to provide the Granzotto'392 system with the same advantage of releasably engaging the device around a user's neck and allowing for proper vertical

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adjustment of the electrodes to record an electrocardiographic complex (motivation to combine provided by Reinhold'823, column 5, lines 1-20).

Response to Arguments

5. Applicant's arguments, see paragraph 3 of page 4, filed 2 November 2007, with respect to the rejection of claims 1-11 under 35 U.S.C. §101 have been fully considered and are persuasive. The §101 rejection of claims 1-11 has been withdrawn.

6. Applicant's arguments filed 2 November 2007 with respect to the rejection of claims 1-3 and 79 under 35 U.S.C. §102(b) as anticipated by Granzotto have been fully considered but they are not persuasive, and are additionally or alternatively moot in view of a new grounds of rejection made in view of a different interpretation of the previously applied art, as well as newly found prior art.

Applicant's specific argument that Granzotto fails to disclose or suggest a switching means comprising push-down switches located in the electrodes is considered to be fully addressed in the preceding paragraphs.

In response to applicant's argument that neither Granzotto nor Reinhold discloses a switching means as recited in claim 1, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Alternatively, Granzotto has been shown to disclose switching contacts on swivel arms 19 in column 4, lines 7-27 that satisfy the argued claim limitation.

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7. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Granzotto and Reinhold are directed to devices which collect electrocardiographic data through temporary external application of a medical monitoring device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

15 November 2007

/George Manuel/
Primary Examiner